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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,260	03/26/2001	Nicholas J. Schork	GENSET.076C1	9223

23557 7590 01/14/2005

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EXAMINER

LIN, JERRY

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/818,260		SCHORK ET AL.	
	Examiner		Art Unit	
	Jerry Lin		1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,7,40,41 and 46-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,7,40,41 and 46-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 18, 2004 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The disclosure of Stanton, Jr., relied upon in this rejection, receives benefit to at least the filing date of July 20, 1999, of parent application No. 09/357743. As such, Stanton, Jr. is valid prior art under 103(a) against the instant claims. The disclosure of Blumenfeld et al., also relied upon in this rejection, receives benefit to at least the filing date of June 4, 1999. As such, Blumenfeld et al. is valid prior art under 103(a) against the instant claims.

Claims 1, 4, 7, 40, 41, and 46 - 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanton, Jr. (US 2002/0039990), and taken in view of Blumenfeld et al. (US 6,759,192) and taken further in view of Jeffreys (US 5,811,235).

Stanton, Jr. teaches a method of determining the statistical significance of a difference between haplotype frequency profiles of at least two groups of individual which includes determining the combined likelihood that the two groups of individuals are derived from the same distribution of haplotypes, determining the sum of the separate likelihoods that each of the two groups of individuals are derived from the same distribution of halpotypes, and determining the difference of the sum and combined likelihood (page 65, paragraph [0825]).

Stanton, Jr. does not teach obtaining the haplotypes of individuals for each group by genotyping the same chromosome, randomly permuting the haplotypes between groups to determine the probability that the groups do not come from the same

distribution of haplotypes, or calculating all possible single-haplotype chi-square tests. Nor does Stanton teach using a binary code to identify the haplotypes of all individuals.

Blumenfeld et al. teach a method of determining the haplotype frequencies of a population which include obtaining haplotypes for all individuals in each of two groups of individuals by genotyping the same gene which is located on the same chromosomal segment (column 77, lines 43-49; column 154, lines 43-53; column 154, line 63- column 155, line 9); randomly permuting the haplotypes between groups to determine the probability that the groups do not come from the same distribution of haplotypes (column 88, lines 39-53); assessing the statistical significance of individual haplotypes using an odds ratio (column 88, line 64 - column 89- line 5). Regarding claim 40 in particular, Blumenfeld teaches calculating all possible single-haplotype chi-square tests (column 87, line 65 – column 88, line 16).

Jeffreys teaches a method of characterizing genomic DNA which includes providing binary codes for an allele or a haplotype (column 2, lines 38- column 3, line 7); and using that code to generate an array (column 16, lines 38-43, Fig. 1A).

Both Blumenfeld et al. and Stanton teach implementing their methods using computer programs and computer storage devices (Stanton, page 65, paragraph [0825]; Blumenfeld, column 132, line 38 - column 133, line 2).

It would have been obvious to one of ordinary skill in the art to combine the references of Stanton, Blumenfeld et al., and Jeffreys. Blumenfeld et al.'s disclosed methods support Stanton's stated goal of identifying variances within genes to determine if a drug is safe for patients (Stanton, page 1, paragraph [0006]).

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Blumenfeld's methods provide the advantage of determining the statistical significance of a correlation between a phenotype and genotype (Blumenfeld, column 87, lines 57-65) including the phenotype of drug response. In addition, it would be obvious to add Jefferys method to binary coding of alleles to the above references given that both Blumenfeld and Stanton use computer systems to implement their methods (Stanton, page 65, paragraph [0825]; Blumenfeld, column 132, line 38 - column 133, line 2) and Jefferys's statement that a system of generating a large number of unambiguous DNA phenotypes in a database would be advantageous for comparing frequencies and would require binary coding (Jefferys, column 2, line 38-65).

Status of the Claims

Claims 1, 4, 7, 40, 41, and 46 – 50 are pending.

Claims 1, 4, 7, 40, 41, and 46 – 50 are rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:30-7:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ardin H. Marschel 1/8/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER

JL